APR - 4 2011

EXHIBIT 1

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K103617

1. Submitter's Identification:

K-jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien, 248, Taiwan
Tel: +886-2-22991378
Fax: +886-2-22331386

Contact: Mr. Jason Cheng
Date Summary Prepared: November 30, 2010

2. Name of Device:

K-jump Health Co., Ltd. Digital Forehead Thermometer, Model KD-2201 & DK-2210

Regulation Number: 21 CFR 880.2910
Regulation Name: Thermometer, Electronic, Clinical
Regulatory Class: II
Product Code: FLL

3. Predicate Device Information:

- K070491, Digital Forehead Thermometer, Model KD-2200, K-jump Health Co., Ltd., Taipei, Taiwan

4. Device Description:

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The Digital Forehead Thermometers, Model KD-2201 & KD-2210, consist of a probe with thermister sensor and stainless steel plate, a PC board with ASIC circuits, a LCD display, a plastic main body, an ON/OFF power key, a buzzer and two AAA type batteries for the determination of human body temperature.

The tip of probe is made with a thermister sensor and stainless steel plate which may sense the temperature changing rapidly. The electronic signal was transferred to ASIC circuit on PC board through sensor on probe. The LCD displays the predictive temperature or last temperature recorded and warning information during measurement. All components assemble on the plastic main body. There is only one ON/OFF button to power on or off the device. The buzzer may sound during operation or end of the temperature measuring. The device is powered by DC voltage of two AAA type batteries

Press the power button may turn on the thermometer and the full screen of LCD will be displayed for two seconds with a "beep-beep" sound and flashing hourglass icon. After that, LCD will be displayed the measuring scale "℃ or ℉" and the hourglass icon disappeared. Then, the thermometer is ready for measurement. Place the probe to the temple and let the sensor touching patient's skin gently. The thermometer will start measuring automatically. Six seconds later, a "beep-beep" sound will be heard and the reading will be displayed when measuring completed. For the next measurement, wait for the hourglass stop flashing and disappeared before place the probe to patient's temple again. Press power button again may turn off the thermometer or the thermometer will turn off itself in one minute if not use.

The compact, small and light-weight design, the K–jump Health Co, Ltd. Digital Forehead Thermometers, Model KD-2201 & KD-2210, enable to provide safe and reliable results and offers a very good clinical accuracy for human body temperature measurement.

5. Intend Use:

K–jump Health Co, Ltd. Digital Forehead Thermometers, Model KD-2201 & KD-2210, are intended to measure the human body temperature using the forehead as measurement site. They can be used with adult or pediatric patients.

6. Comparison to Predicate Devices:

The subject device is substantially equivalent to the predicate devices, K070491, Digital Forehead Thermometer Model KD-2200. The substantial equivalence chart is provided as follows:

Characteristics	Subject Devices KD-2201	KD-2210	Predicate Device (KD-2200, K#070491)
Sensor Type	Thermister		Thermister
Number of Sensor	One (Skin Temperature Sensor)		Two (Skin & Ambient Temperature Sensors)
Microcontroller	Sonix SN8P1919		Sonix SN8P1909
Measuring Range	35.0℃~42.0℃ (95.5℉~107.6℉)		32.2°C – 43.3°C (90°F – 109.9°F)
Display Resolution	0.1℃ (0.1℉)		0.1℃ (0.1℉)
C/F Switchable	Yes		Yes
Measuring accuracy	±0.1℃ (35.0℃~42.0℃)		±0.1℃ 34.0°C – 42.0°C (93.2°F – 107.6°F) ±0.2℃other range
Display	LCD display		LCD display
Measurement Site	Temporal artery area of forehead		Temporal artery area of forehead
Key	One button		One button
Memory	Nine sets		One set (Nine sets optional)
Power source	Two 1.5V AAA batteries		Two 1.5V AA batteries
Low battery Indication	Replace the battery if the low battery indication appears		Replace the battery if the low battery indication appears
Operating condition	10℃ ~ 40℃ (50°F – 104.0°F) 15-95% RH, non-condensing.		16℃ ~ 40℃ (60.8°F – 104.0°F) < 95% RH, non-condensing
Storage condition	-25℃ ~ 50℃ (-13°F – 122°F) 15-95% RH, non-condensing		-25℃ ~ 55℃ (-13°F – 131°F) < 95% RH, non-condensing
Dimension	105x46x44 mm	127x33x29mm	92x45x35 mm
Weight	73g (including batteries)	46g (including batteries)	55g (including batteries)

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following performance testing was conducted:

- The Digital Forehead Thermometers, KD-2201 & KD-2210, are complied with voluntary

standards includes ASTM E 1112-00 and EN 12470-3.

- The recognized consensus standards for safety of medical electrical equipment: IEC 60601-1 with amendments for safety and IEC 60601-1-2 for electromagnetic compatibility are complied.

- Guidance documents included the "FDA Guidance on the Content of Premarket Notification 510(k) submissions for Clinical Electronic Thermometers".

8. Discussion of Clinical Tests Performed:

The subject devices are modified from the predicative device, Mode KD-2200. They use the same technical and design principle and have the same intended use. The differences between them are slightly. The ASTM E 1112-00 and EN 12470-3 test reports show the subject devices meet the all necessary requirements. The performance of subject and predicative devices are the same. Base on above discussion the clinical test is not necessary for the subject devices.

9. Conclusions:

K-jump Health Co., Ltd. Digital Forehead Thermometers, Model KD-2201 & KD-2210, have the same intended use and similar characteristics as the predicate device. Moreover, the subject device demonstrates product safety by successful completion of testing to the IEC60601-1 standard and electromagnetic standard, IEC 60601-1-2. The performance test demonstrates the KD-2201 & KD-2210 meet the ASTM E 1112-00 and EN 12470-3 standards and concludes that any differences in their characteristics do not rise any safety and effectivness issues.

From the above information we conclude the the subject devices, KD-2201 & KD-2210, are substantially equivalent to the predicate device, KD-2200.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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Mr. Jason Cheng
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Re: K103617
Trade/Device Name: Digital Forehead Thermometer, Model KD-2201 & KD-2210
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: March 3, 2011
Received: March 7, 2011

Dear Mr. Cheng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

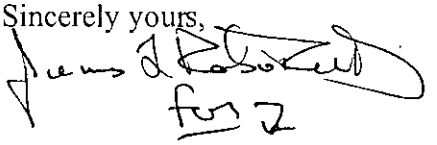
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
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Radiological Health

Enclosure

EXHIBIT B

Indications for Use Statement

510(k) Number (if known): K103617

Device Name: K-jump Health Co., Ltd. Digital Forehead Thermometer, Model KD-2201 & KD-2210

Indications for Use:

K–jump Health Co, Ltd. Digital Forehead Thermometers, Model KD-2201 & KD-2210, are intended to measure the human body temperature using the forehead as measurement site. They can be used with adult or pediatric patients.

Prescription Use _____ (Per 21 CFR 801 Subpart D) OR Over-The Counter Use ___x___ (21 CFT 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 4/4/4

Division Sign-Off)
ivision of Anesthesiology, General Hospital
fection Control, Dental Devices

510(k) Number: K103617